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5	REFO	RE THE
6	BOARD OF	PHARMACY CONSUMER AFFAIRS
7		CALIFORNIA
8	In the Matter of the Accusation Against:	Case No. 3480
9	SOUTHWOOD PHARMACEUTICAL	OAH No. 2011060986
11	60 Empire Drive Lake Forest, CA 92630 Wholesale Permit No. WLS 4078	DEFAULT DECISION AND ORDER
12	JOHN SEMPRE	[Gov. Code, §11520]
13	60 Empire Drive Lake Forest, CA 92630 Pharmacist License No. RPH 25420	
14	MEDIPHARM RX INC.	
15	4607 N. Clark Avenue Tampa, FL 33614	
16	Non-Resident Pharmacy License No. NRP 670	
17	UNITED PRESCRIPTION SERVICES	
18	2304 East Fletcher Avenue Tampa, FL 33612	
19	Non-Resident Pharmacy License No. NRP 466	
20	MEDCENTER INC.	
21 22	6935 S. Carter Road, Suite 6 and 7 Lakeland, FL 33813	
23	Non-Resident Pharmacy License No. NRP 752	
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25	Respondents.	
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FINDINGS OF FACT

- 1. On or about August 10, 2010, Complainant Virginia Herold, in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, filed Accusation No. 3480 against UNITED PRESCRIPTION SERVICES. (Respondent UPS) before the Board of Pharmacy. (Accusation attached as Exhibit A.)
- 2. On or about January 5, 2006, the Board of Pharmacy (Board) issued Non-Resident Pharmacy License No. NRP 466 to Respondent UPS. The Non-Resident Pharmacy License expired on January 1, 2005, and has not been renewed. This lapse in licensure, however, pursuant to Business and Professions Code section 118(b) does not deprive the Board of its authority to institute or continue this disciplinary proceeding.
- 3. On or about August 24, 2010, Respondent UPS was served by Certified and First Class Mail copies of the Accusation No. 3480, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7) at Respondent's address of record which, pursuant to Business and Professions Code section 4100, is required to be reported and maintained with the Board. Respondent's address of record was and is: 2304 East Fletcher Avenue, Tampa, FL 33612.
- 4. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505, subdivision (c) and/or Business & Professions Code section 124.
- 5. On or about August 30, 2010, the Domestic Return Receipt article no. 7160 3901 9848 8386 7169 was returned by the U.S. Postal Service with an illegible signature, dated August 26, 2010. The address on the documents was the same as the address on file with the Board. Respondent UPS failed return the Notice of Defense, and therefore, has not availed itself of the right to appear at hearing.
 - 6. Government Code section 11506 states, in pertinent part:
 - (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense, and the notice shall be deemed a specific denial of all parts of the accusation not expressly admitted. Failure to file a notice of defense shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

- 7. Respondent UPS failed to file a Notice of Defense within 15 days after service upon them of the Accusation, and therefore waived the right to a hearing on the merits of Accusation No. 3480.
 - 8. California Government Code section 11520 states, in pertinent part:
 - (a) If the respondent either fails to file a notice of defense or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent.
- 9. Pursuant to its authority under Government Code section 11520, the Board finds Respondent UPS is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Accusation No. 3480, finds that the charges and allegations in Accusation No. 3480, are separately and severally, found to be true and correct by clear and convincing evidence.

DETERMINATION OF ISSUES

- 1. Based on the foregoing findings of fact, Respondent UPS has subjected its Non-Resident Pharmacy License No. NRP 466 to discipline.
 - 2. The agency has jurisdiction to adjudicate this case by default.
- 3. The Board of Pharmacy is authorized to revoke Respondent UPS' Non-Resident Pharmacy License based upon the following violations alleged in the Accusation which are supported by the evidence contained in the Default Decision Evidence Packet in this case:
- a. Respondent United Prescription Services (UPS) is subject to disciplinary action under section 4402(e), in conjunction with California Code of Regulations section 1708.2, in that Respondent UPS' license with the Florida Board of Pharmacy (PH17181) was "closed;" and Respondent UPS' California license expired on May 1, 2005, and Respondent UPS failed to renew its license and failed to notify the Board of its discontinuance of business under its non-resident pharmacy license no. NRP 466, in violation of pharmacy law.

	ODDED		
1	ORDER		
2	IT IS SO ORDERED that Non-Resident Pharmacy License No. 466, heretofore issued to		
3	Respondent UPS, is revoked.		
4	Pursuant to Government Code section 11520, subdivision (c), Respondent UPS may serve a		
5	written motion requesting that the Decision be vacated and stating the grounds relied on within		
6	seven (7) days after service of the Decision on Respondent. The agency in its discretion may		
7	vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.		
8	This Decision shall become effective on November 19, 2012.		
9	It is so ORDERED ON October 19, 2012.		
10	BOARD OF PHARMACY		
11	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
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13	la (. Wussi		
14	By STANLEY C. WEISSER		
15	STANLEY C. WEISSER Board President		
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17	70611613.DOCX DOJ Matter ID: SD2009804825		
18	Attachment:		
19	Exhibit A: Accusation		
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Exhibit A

Accusation

1 2 3 4 5 6 7 8	EDMUND G. BROWN JR. Attorney General of California JAMES M. LEDAKIS Supervising Deputy Attorney General ERIN M. SUNSERI Deputy Attorney General State Bar No. 207031 110 West "A" Street, Suite 1100 San Diego, CA 92101 P.O. Box 85266 San Diego, CA 92186-5266 Telephone: (619) 645-2071 Facsimile: (619) 645-2061 Attorneys for Complainant	
9		RE THE PHARMACY
10	DEPARTMENT OF O	CONSUMER AFFAIRS
10	STATE OF C	CALIFORNIA
12	In the Matter of the Accusation Against:	Case No. 3480
13	SOUTHWOOD PHARMACEUTICAL 60 Empire Drive	
14	Lake Forest, CA 92630 Wholesale Permit No. WLS 4078	ACCUSATION
15	JOHN SEMPRE	
16	60 Empire Drive Lake Forest, CA 92630	
17	Pharmacist License No. RPH 25420	
18	MEDIPHARM RX INC. 4607 N. Clark Avenue	
19	Tampa, FL 33614 Non-Resident Pharmacy License No.	
20	NRP 670	
21	UNITED PRESCRIPTION SERVICES 2304 East Fletcher Avenue	
22	Tampa, FL 33612 Non-Resident Pharmacy License No.	
23	NRP 466	
24	MEDCENTER INC. 6935 S. Carter Road, Suite 6 and 7	
25	Lakeland, FL 33813 Non-Resident Pharmacy License No.	
26	NRP 752	
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28	Respondents.	
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PARTIES

- 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about March 25, 2002, the Board of Pharmacy issued Original Wholesale Permit Number WLS 4078 to Southwood Pharmaceutical, Inc. (Respondent Southwood). The Original Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2011, unless renewed.
- 3. On or about March 7, 1968, the Board of Pharmacy issued Pharmacist License Number RPH 25420 to John Sempre (Respondent Sempre). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2011, unless renewed.
- 4. On or about January 5, 2006, the Board of Pharmacy issued Non-Resident Pharmacy License Number 670 to Medipharm Rx Inc. (Respondent Medipharm). The Non-Resident Pharmacy License expired on January 1, 2007, and has not been renewed.
- 5. On or about May 3, 2002, the Board of Pharmacy issued Non-Resident Pharmacy Number 466 to United Prescription Services (Respondent UPS). The Non-Resident Pharmacy License expired on May 1, 2005, and has not been renewed.
- 6. On or about October 3, 2006, the Board of Pharmacy issued Non-Resident Pharmacy Number 752 to Medcenter Inc. (Respondent Medcenter). The Non-Resident Pharmacy License expired on October 1, 2007, and has not been renewed.

JURISDICTION

- 7. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 8. Section 4300 of the Code provides that every license issued by the Board may be suspended or revoked.

	9.	Section 4402(e) of the Code provides, in pertinent part, that any license, other than a
pharr	nacist	license, issued by the board may be canceled by the board if the license is not renewed
withi	n 60 c	days after its expiration. Any license canceled under this subdivision may not be
reissı	aed. I	nstead, a new application will be required.

Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

STATUTORY PROVISIONS

11. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable

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Section 4022 of the Code states 12.

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"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

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(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import;

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20. **Hydrocodone with acetaminophen** (brand name **Vicodin**) is a Schedule III controlled substance as designated by Health and Safety Code section 11056(e) (4) and a dangerous drug as designated by Business and Professions Code section 4022. It is a narcotic indicated for moderate pain.¹

FACTS

- 21. On March 25, 2002, the Board issued a drug wholesale permit, WLS 4078, to Respondent Southwood. Respondent Sempre was the owner and designated representative in charge at Southwood. The Drug Enforcement Administration (DEA) also issued Respondent Southwood a DEA Certificate of Registration to purchase and sell controlled substances as a repackager, RS0204898.
- 22. Respondent Southwood had a repackaging license with the Food and Drug Administration (FDA), license no. 2027647, and with the Department of Health Care Service, State Food and Drug Branch, license no. 42125. Respondent Southwood repackaged oral dose generic drugs into common prescription quantities. Respondent Southwood's customers included physicians who specialized in treating work-related injuries, pain management, urgent care facilities, specialty clinics and retail pharmacies.
- 23. In or around July 2006, the DEA began conducting an investigation into Respondent Southwood when the DEA received information that Respondent Southwood's sales of hydrocodone products increased from 7,000 dosage units per month to 3,700,000 dosage units per month.
- 24. In or around July 2006, M.M., Chief of the Office of Diversion Control's E-Commerce Section from the DEA, conducted a conference call with Robert Goodrich, the Director of Operations and Regulatory Affairs and Grace Gonzalez, Operations Manager of Respondent Southwood.

¹ By itself, hydrocodone is a Schedule II controlled substance. Respondent did not, however, distribute Schedule II hydrocodone. Throughout this Accusation, the term hydrocodone refers to those Schedule III controlled substances which contain hydrocodone, pursuant to Health and Safety Code section 11056, and a dangerous drug as designated by Business and Professions Code section 4022.

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- 25. M.M. discussed the requirement under Federal Law that in order for a prescription to be valid, it must be issued in the usual course of medical practice, and that an internet questionnaire alone is not sufficient to legally prescribe controlled substances.
- 26. Respondent Southwood was advised that factors necessary to establish a bona fide doctor-patient relationship included that the patient have a medical complaint; a history be taken of the patient; a physical examination be conducted; and that there be a nexus between the complaint, the history, the examination, and the drug being prescribed.
- 27. Mr. Goodrich was also informed that a pattern of drugs being distributed to pharmacies which were diverted controlled substances demonstrated a lack of effective controls against diversion by the distributor.
- 28. Mr. Goodrich was also advised that any distributor selling controlled substances that are being dispensed outside of the course of professional practice must stop the distribution immediately, and that Respondent Southwood had an obligation to ensure the products distributed were used for legitimate medical purposes.
- 29. After the conference with the DEA, Respondent Southwood continued to distribute large quantities of hydrocodone to numerous internet pharmacies.
- 30. On or about December 6, 2006, R.P., Acting Special Agent in Charge of the DEA, Los Angeles Field Division, announced the immediate suspension of Respondent Southwood's DEA Certificate of Registration. Respondent Southwood had been the subject of a DEA investigation alleging that Respondent Southwood sold large quantities of controlled substances to internet pharmacies.
- 31. For the purpose of the DEA's investigation, the term "internet pharmacy" was referred to as a pharmacy that filled a prescription issued by physician without the physician having entered into a legitimate doctor-patient relationship under existing professional standards.²

² Typically, a person seeking controlled substances goes to an internet site, fills out a questionnaire which requests basic medical, payment and shipping information, and a specific drug. Some websites may require the patient submit a medical record, which is easily falsified. The customer's information is forwarded to a physician either contracted or employed by the website, who reviews the information and issues a prescription, either with or without the benefit of a perfunctory telephone consultation, but always without having conducted a face-to-face (continued...)

- 32. On or about December 29, 2006, the Board received information from the DEA notifying the Board that Respondent Southwood's license with the DEA was suspended on the basis of diversion of controlled substances. Respondent Southwood was the subject of a DEA investigation alleging that the company sold large quantities of controlled substances to internet
- 33. On or about June 22, 2007, Administrative Law Judge (ALJ) Michele Leonhart ordered the DEA Certificate of Registration, RS0204898, issued to Respondent Southwood, be revoked and the pending application of Respondent Southwood for renewal of its registration be denied. ALJ Leonhart concluded that Respondent Southwood's continued registration constituted an imminent danger to public health and safety. The order was effective immediately.
- 34. The DEA website <u>www.deadiversion.usdoj.gov</u> posted on the Federal Register Notices, dated July 3, 2007, Volume 72, Number 127, Docket No. 07-7, titled: "Southwood Pharmaceuticals, Inc., Revocation of Registration." The docket stated the following:
- a. On November 30, 2006, the Deputy Administration of the DEA issued an Order to Show Cause and Immediate Suspension of Registration to Southwood. The Order immediately suspended Southwood's DEA Certificate of Registration, RS0204898, based on preliminary findings that continued registration constituted an imminent danger to the health and safety of the public due to the substantial likelihood that Southwood would continue to supply pharmacies that diverted large quantities of controlled substances;
- b. The Show Cause Order alleged that between November 2005 and August 2006, Southwood sales to pharmacies for hydrocodone products increased from approximately 7,000 dosage units per month to approximately 3,000,000 dosage units per month and the increase was directly attributable to supplying controlled substances to pharmacies that Southwood should have known were engaged in the widespread diversion of controlled substances. The Show

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review of the person's medical history and a physical exam. The prescription is then either forwarded to the pharmacy or downloaded electronically by the pharmacy; the pharmacy then fills the prescription and ships it to the customer.

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Cause Order alleged several customers were distributing large amounts of hydrocodone-based orders placed by customers using various websites.

- c. The Show Cause Order specifically alleged that from December 12, 2005 to August 31, 2006, Southwood distributed approximately 8,671,000 dosage units of hydrocodone products to Medipharm-Rx, Inc., and did so under circumstances that clearly indicated that Medipharm, whose owner also owned an internet website, engaged in the diversion of controlled substances. Medipharm was soliciting orders for controlled substances, used practitioners who issued prescriptions outside of their usual professional practice, and Medipharm's orders were of an unusual size and frequency, deviating from the normal pattern. In addition to Medipharm, Southwood also sold drugs to fourteen pharmacies with similar suspicious circumstances. The Show Cause Order alleged that Southwood had repeatedly supplied excessive quantities of hydrocodone to pharmacies it knew or should have known were diverting hydrocodone.
- d. The next Show Cause Order alleged that on July 17, 2006, the Office of Diversion Commerce Section held a conference call with Southwood representatives to discuss the distribution of controlled substances to internet pharmacies. During the call, DEA officials allegedly presented Southwood with information on the characteristics of internet pharmacies and the nature of their illegal activities. In August 2006, Southwood proceeded to distribute large quantities of hydrocodone to five different internet pharmacies and allegedly failed to maintain effective control against diversion, and Southwood's continued registration would be inconsistent with the public interest.
- e. From February 5 through February 8, 2007, a hearing was conducted in Arlington, VA., by ALJ Gail Randall. On March 30, 2007, the ALJ issued her recommended decision, concluding that the DEA had proved that Southwood's continued registration to handle hydrocodone would be against the public interest. The ALJ concluded that Southwood had kept an open dialogue with the DEA and had attempted to come into compliance with the DEA's regulations and revocation of Southwood's DEA registration was too severe a remedy. The ALJ noted that Southwood had hired an experienced officer who would be making the final decisions concerning compliance measures, providing an increased level of protection of the public interest.

Therefore, the ALJ recommended that Southwood's authority to handle hydrocodone products be revoked while allowing Southwood to retain its authority to handle other controlled substances. The ALJ recommended the DEA monitor Southwood to ensure it complied with both the proposed restrictions and Southwood's decision to cease distributing to Florida-based internet pharmacies.

- f. Thereafter, the U.S. Government filed exceptions, stating that Southwood also distributed excessive quantities of other controlled substances including phentermine and alprazolam. The Government further argued that under the day-to-day leadership of Southwood's new Chief Operating Officer (COO), Southwood continued to constructively distribute controlled substances to its physician clients after its registration was suspended, refuting the ALJ's hypothesis that the COO would effectively manage Southwood's compliance program.
- g. On May 8, 2007, the ALJ forwarded the record to Michele Leonhart, Deputy Administrator, who adopted the ALJ's findings, but concluded that the ALJ's proposed remedy was insufficient to protect the public interest, and that Respondent's sales of extraordinary quantities of controlled substances to entities which it had reason to know were diverting drugs caused extraordinary harm to public health and safety. Therefore, Southwood's registration was revoked and its pending renewal application was denied.
- 35. The DEA's findings that lead to the revocation of Southwood's DEA registration, listed in Docket No. 07-7, also included the following:
- a. From August 2005, the DEA reviewed the ARCOS (Automation of Reports and Consolidated Orders System) reports submitted by Southwood. Southwood had sold 3,949,454 dosage units of hydrocodone products, of which, 3,882,507 dosage units (98%) were sold to practitioner customers and 29,940 dosage units (0.75%) to pharmacy customers, for an average of 7,485 dosage units per month.

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- b. On December 7, 2005, Southwood entered a new line of business- supplying internet pharmacies- by selling hydrocodone to Medipharm-Rx., Inc., a Florida-based internet pharmacy (Respondent Medipharm). Over the ensuing months, Southwood acquired numerous additional internet pharmacy customers to whom it repeatedly sold large quantities of hydrocodone.
- c. On December 7, 2005, Southwood began supplying Medipharm-Rx Inc. and other internet pharmacies with hydrocodone products. From December 2005 through October 2006, Southwood supplied Medipharm with 11,130,700 dosage units of hydrocodone products, an average of 1,011,882 dosage units of hydrocodone products per month, constituting 99% of drug sales to Medipharm.
- d. The Florida Board of Pharmacy, website www.doh.state.fl.us, revealed that Medipharm-Rx had two licenses (PH21003 and PH21000) at the same address that both listed "closed" as the license activity status. The California State Board of Pharmacy, website www.pharmacy.ca.gov, listed Medipharm-Rx, Inc., license no. NRP670, as expired on January 1, 2007. Medipharm failed to renew their non-resident pharmacy license, had a "delinquent" status, and failed to submit a discontinuance of business with the Board of Pharmacy.
- e. On December 19, 2005, Southwood began supplying Accumed Rx., Inc., another internet Florida-based pharmacy customer. From December 2005 to November 2006, Southwood sold 5,884,212 dosage units of hydrocodone products to Accumed, constituting 99% of drug sales to Accumed.
- f. The Florida Board of Pharmacy revealed that Accumed-Rx had one license (PH21402) listed "closed" as the license activity status. The California State Board of Pharmacy showed no listing for Accumed-Rx.
- g. On December 21, 2005, Southwood started supplying Avee Pharmacy, another internet pharmacy. From December 2005 through November 2006, Southwood supplied Avee with 6,795,110 dosage units of hydrocodone products plus 238,140 dosage units during the first five days of December 2006. From December 2005 to June 2006, controlled substances constituted 100% of sales to Avee. On or about November 17, 2006, Southwood notified Avee

by letter effective December 15, 2006, Southwood would not supply Avee (whose registration had been continued on a day-to-day basis past its expiration date and not renewed) unless it obtained a renewal of its registration. Between November 17, 2006 to December 15, 2006, Southwood supplied Avee approximately 6,795,110 dosage units of hydrocodone products.

- h. The Florida Board of Pharmacy revealed that Avee Pharmacy had two licenses (PH19760 and PH21935) both listed "closed" as the license activity status. The California State Board of Pharmacy listed Avee Pharmacy as a non-resident pharmacy, license no. NRP657, as "cancelled."
- i. On January 4, 2006, Southwood began supplying United Prescription Services, Inc., (Respondent UPS), another internet pharmacy. From February 2006 to November 2006, Southwood sold 929,880 dosage units to UPS, a monthly average of 92,988 dosage units. On November 17, 2006, Southwood notified UPS that it would stop supplying UPS if UPS did not obtain a renewal of its registration. From November 21, 2006 through December 5, 2006, Southwood sold 158,280 dosage units of hydrocodone to UPS.
- j. The Florida Board of Pharmacy revealed that UPS had two licenses (PH17181 and PH24549) the first, listed as "closed" as the license activity status, and the second as "null/void." The California State Board of Pharmacy listed UPS as a non-resident pharmacy, license no. NRP466, as "delinquent." UPS' license was issued May 3, 2002 and expired on May 1, 2005. UPS failed to renew their non-resident pharmacy license, had a "delinquent" status, and failed to submit a discontinuance of business with the Board of Pharmacy.
- k. On January 25, 2006, Southwood began servicing Bi-Wise Drugs, Inc. (Bi-Wise), another internet pharmacy customer. From January 25, 2006 through October 2006, Southwood sold 1,171,500 dosage units to Bi-Wise, a monthly average of 117,150 dosage units.
- 1. Bi-Wise had three licenses with the Florida Board of Pharmacy (PH21960, PH18991, and PH22277), all listed as "closed." Bi-Wise was also doing business as Bi-Wise Pharmacy and Compounding. Bi-Wise was not listed as a non-resident pharmacy with the California State Board of Pharmacy.

- m. On February 16, 2006, Southwood began servicing Vin-Kash, dba Medicom Rx (Medicom), another internet pharmacy customer. From February 2006 through November 2006, Medicom purchased 1,902,810 dosage units of hydrocodone from Southwood, a monthly average of 190,281 dosage units.
- n. The Florida Board of Pharmacy listed Medicom's license (PH21018) as "delinquent." Medicom was not licensed in California as a non-resident pharmacy.
- o. On February 20, 2006, Southwood began servicing Discount Mail Meds (Discount), another internet pharmacy customer. From February 2006 through November 2006, Discount purchased 3,303,240 dosage units of hydrocodone products from Southwood, a monthly average of 330,324 dosage units. Discount was not listed on the Florida Board of Pharmacy website as a pharmacy licensed in Florida; nor was it listed on the California State Board of Pharmacy website as either a pharmacy or a non-resident pharmacy licensed in California.
- p. On February 22, 2006, Southwood began servicing Universal Rx (Universal). From February 2006 to November 2006, Universal purchased 3,086,790 dosage units of hydrocodone products from Southwood, a monthly average of 308,679 dosage units. On November 17, 2006, Southwood notified Universal that effective December 15, 2006, it would stop supplying the pharmacy unless it obtained a renewal of its registration. On November 30, 2006, Southwood stopped shipping to Universal.
- q. The Florida Board of Pharmacy website listed Universal (license no. PH19719) as "delinquent." Universal was not listed on the California State Board of Pharmacy website as a pharmacy or a non-resident pharmacy licensed in California.
- r. On March 3, 2006, Southwood began doing business with Medcenter, Inc. (Respondent Medcenter), an entity owned by the same person as Medipharm. From March 2006 through October 2006, Medcenter purchased 2,664,500 dosage units of hydrocodone products from Southwood, a monthly average of 333,062 dosage units. In November 2006, when Medcenter's DEA registration was suspended, Southwood sold Medcenter 313,680 dosage units of hydrocodone products during the first two weeks of November.

- s. The Florida Board of Pharmacy website listed Medcenter (license no. PH21072) as "delinquent." The California State Board of Pharmacy listed Medcenter Pharmacy as a non-resident pharmacy, license no. NRP752, as "delinquent." Medcenter's license was issued October 3, 2006 and expired on October 1, 2007. Medcenter failed to renew their non-resident pharmacy license, had a "delinquent" status, and failed to submit a discontinuance of business with the Board of Pharmacy.
- t. On March 9, 2006, Southwood began doing business with CRJ Pharmacy, Inc. (CRJ). From March 2006 to October 2006, Southwood sold CRJ 638,420 dosage units of hydrocodone products, a monthly average of 79,803 dosage units.
- u. The Florida Board of Pharmacy website listed CRJ (license no. PH21511) as "closed." CRJ was not licensed in California as a non-resident pharmacy.
- v. In May 2006, Southwood began doing business with Akshar Chemists, dba Medicine Shoppe. From May 2006 to November 2006, Southwood sold Medicine Shoppe 513,555 dosage units of hydrocodone products, a monthly average of 73,365 units.
- w. The Florida Board of Pharmacy website listed Medicine Shoppe (license no. PH18507) as "closed." Medicine Shoppe was not licensed in California as a non-resident pharmacy.
- x. In May 2006, Southwood began doing business with Grand Pharmacy (Grand). From May 2006 to November 2006, Southwood sold Grand 1,008,720 dosage units of hydrocodone products, a monthly average of 144,102 units.
- y. The Florida Board of Pharmacy website listed Grand (license no. PHY21636) as "closed." Grand was not licensed in California as a non-resident pharmacy.
- z. In July 2006, Southwood began doing business with Q-R-G, Inc., dba Duane's Discount Group (Duane's). From July to November 2006. From July 2006 to November 2006, Southwood sold Duane's 959,040 dosage units of hydrocodone products, a monthly average of 191,808 units.
- aa. The Florida Board of Pharmacy website listed Duane's (license no. PH21512) as "closed." Duane's was not licensed in California as a non-resident pharmacy.

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- a. Southwood's due diligence in approving a new customer was limited to verifying that the customer had a state license and a DEA registration. Based solely on its verification of the customer's DEA registration and state license, Southwood would commence shipping large quantities of controlled substances to various internet pharmacies.
- On or about September 6, 2007, an inspector for the California State Board of Pharmacy went to Southwood to conduct an inspection and investigation. Respondent Sempre was present during this investigation. At the end of the inspection, a copy of the inspection report was signed by Respondent Sempre. Two corrections were ordered to revise policy and procedures for Southwood's standard operations procedure: documentation of how long records of acquisition and disposition were retained; and revision of standard operations procedure for theft and loss to include contacting the Board within 30 days.
- On or about January 6, 2009, Southwood's application for a new DEA registration number was approved, and on January 7, 2009, DEA registration number RS0377691 was issued with restrictions. (Southwood's original registration number DEA RS0204898 remained revoked). Southwood's new DEA registration number authorized Southwood to sell Schedule III, IV and V controlled substances to hospitals, clinics, and physicians dispensing from their offices. Southwood was not given authorization to sell to pharmacies.

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FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Violation of California and United States Code)

39. Respondent Southwood is subject to disciplinary action for unprofessional conduct under section 4301, subdivisions (j) and (o) of the Code, in conjunction with Title 21 U.S.C. section 823(d) and 824(a)(4), for violation of the Pharmacy Act and laws regulating controlled substances in that between November 2005 to December 2006, Respondent Southwood sold large quantities of controlled substances to several pharmacies dispensing internet prescriptions for hydrocodone products, a Schedule III controlled substance, and other controlled substances, and continued to sell to these internet pharmacies after Respondent Southwood was educated on the requirements for a valid prescription by the DEA, demonstrating a lack of effective control against diversion. On or about June 22, 2007, Respondent Southwood's DEA controlled substance registration (RS0204898) was revoked and Respondent Southwood's pending application for renewal was denied after conclusion that Southwood's continued registration constituted an imminent danger to public health and safety in violation of pharmacy law and as detailed in paragraphs 21-38, above.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Violation of California and United States Code)

40. Respondent Sempre is subject to disciplinary action for unprofessional conduct under section 4301(j) and (o), and 4022.5 of the Code, in conjunction with Title 21 U.S.C. section 823(d) and 824(a)(4), for violation of the Pharmacy Act and laws regulating controlled substances in that between November 2005 to December 2006, Respondent Southwood sold large quantities of controlled substances to several pharmacies dispensing internet prescriptions for hydrocodone products, a Schedule III controlled substance, and other controlled substances, and continued to sell to these internet pharmacies after Respondent Southwood was educated on the requirements for a valid prescription by the DEA, demonstrating a lack of effective control against diversion. On or about June 22, 2007, Respondent Southwood's DEA controlled substance registration (RS0204898) was revoked and Respondent Southwood's pending application for renewal was denied after conclusion that Southwood's continued registration constituted an imminent danger

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to public health and safety in violation of pharmacy law and as detailed in paragraphs 21-38, above.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

41. Respondents Southwood and Sempre are subject to disciplinary action for unprofessional conduct under section 4301 of the Code in that, by way of the conduct described in paragraphs 21-38 above, Respondents Southwood and Sempre engaged in acts constituting unprofessional conduct not becoming the professional practice of pharmacy.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Renew Non-Resident Pharmacy License)

Respondent Medipharm Rx Inc. is subject to disciplinary action under section 42. 4402(e), in conjunction with California Code of Regulations section 1708.2, in that Respondent Medipharm's license with the Florida Board of Pharmacy (PH21003) was "closed," and expired on February 28, 2007; and Respondent Medipharm's California license expired on January 1, 2007, and Respondent Medipharm failed to renew its license and failed to notify the Board of its discontinuance of business under its non-resident pharmacy license no. NRP670, in violation of pharmacy law and as detailed in paragraphs 21-38, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Renew Non-Resident Pharmacy License)

Respondent United Prescription Services (UPS) is subject to disciplinary action under section 4402(e), in conjunction with California Code of Regulations section 1708.2, in that Respondent UPS' license with the Florida Board of Pharmacy (PH17181) was "closed;" and Respondent UPS' California license expired on May 1, 2005, and Respondent UPS failed to renew its license and failed to notify the Board of its discontinuance of business under its nonresident pharmacy license no. NRP466, in violation of pharmacy law and as detailed in paragraphs 21-38, above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Renew Non-Resident Pharmacy License)

44. Respondent Medcenter, Inc. is subject to disciplinary action under section 4402(e), in conjunction with California Code of Regulations section 1708.2, in that Respondent Medcenter's license with the Florida Board of Pharmacy (PH21072) was "delinquent," and expired on February 28, 2009; and Respondent Medcenter's California license expired on October 1, 2007, and Respondent Medcenter failed to renew its license and failed to notify the Board of its discontinuance of business under its non-resident pharmacy license no. NRP752, in violation of pharmacy law and as detailed in paragraphs 21-38, above.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking or suspending Original Wholesale Permit Number WLS 4078, issued to Respondent Southwood Pharmaceutical, Inc.;
- 2. Revoking or suspending Pharmacist License Number RPH 25420, issued to Respondent John Sempre;
- 3. Revoking or suspending Non-Resident Pharmacy License Number NRP 670, issued to Respondent Medipharm Rx Inc.;
- 4. Revoking or suspending Non-Resident Pharmacy License Number NRP 466, issued to United Prescription Services;
- 5. Revoking or suspending Non-Resident Pharmacy License Number NRP 752, issued to Medcenter Inc.:
- 6. Ordering Respondents Southwood Pharmaceutical, Inc., John Sempre, Medipharm Rx Inc., United Prescription Services and Medcenter Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
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1	7. Taking such other and further action as deemed necessary and proper.
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